5. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

OCT 19 2012

The assigned 510(k) number is: K112605 .

1. Submitted by:	Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL. 60060 Phone: (847) 996-4618; FAX: (847) 996-4655 Contact person: Sharita Brooks Date prepared: August 31, 2011
2. Name of Device:	Trade or proprietary name: Sysmex® XN-Series (XN-10, XN-20) Common name: Automated Hematology Analyzer Classification name: Automated Differential Cell Counter 21 CFR 864.5220 is a Class II device. Product Code: **GKZ** **Related Items:** **Product Code: 81GIF** CELLPACK™ DCL (Diluent) CELLPACK™ DFL (Diluent) **Product Code: 81GGK** LYSERCELL WNR (Lyse) LYSERCELL WDF (Lyse) LYSERCELL WPC (Lyse) **Product Code: 81KJK** FLUOROCELL WNR (Stain) FLUOROCELL WDF (Stain) FLUOROCELL RET (Stain) FLUOROCELL PLT (Stain) FLUOROCELL WPC (Stain) **Product Code: 81KSA** XN CAL (Calibrator) XN CAL PF (Calibrator) **Product Code: 81JPK** XN-Check (Control) XN-Check BF (Control) **Analyzer Components** SA-10 (Auto Sampler for single module) SA-20 (Auto Sampler for two modules) IPU (Information Processing Unit)
3. Predicate Device:	Sysmex® XE-5000Automated Hematology Analyzer

4. Device Description:	The Sysmex® XN-Series modules (XN-10, XN-20) are multi-parameter hematology analyzers intended to perform tests on whole blood samples collected in K_2 or K_3EDTA and body fluids (pleural, peritoneal and synovial) collected in K_2 anticoagulant. It can also perform tests on CSF which should not be collected in any anticoagulant. The instrument consists of four principal units: (1) Two Main Units (XN-10, XN-20) which aspirate, dilute, mix, and analyze blood and body fluid samples; (2) Two Auto Sampler Units (SA-10, SA-20) which supply samples to the Main Unit automatically; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system; (4) Pneumatic Unit which supplies pressure and vacuum from the Main Unit. The XN-Series analyzers perform analysis using the following methods: RF/DC Detection Method, Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. The XN-Series analyzers automatically classify cells from whole blood and body fluids and carry out all processes automatically from aspiration of the sample to outputting the results. The body fluid analysis mode of the XN-Series analyzers uses the 4DIFF scattergram & the RBC distribution obtained from a specialized analysis sequence to calculate & display the WBC (WBC-BF) counts, mononuclear cell (MN) / polymorphonuclear cell (PMN) counts & percentages, TC-BF (Total Count) & RBC (RBC-BF) counts found in the body fluid. Analysis results and graphics are displayed on the IPU screen. They can be printed on any of the available printers or transmitted to a Host computer.
5. Intended Use:	The XN-Series modules (XN-10, XN-20) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC#/%, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K_2 or K_3EDTA anticoagulant and, Serous and Synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.
6. Substantial equivalence-similarities and differences	The following table compares the XN-Series modules (XN-10, XN-20) Automated Hematology analyzers with the XE-5000 Automated Hematology analyzer.
7. Clinical Performance Data:	Studies were performed to evaluate the equivalency of the XN-Series Automated Hematology analyzers (Modules XN-10, XN-20) to the XE-5000 Automated Hematology analyzer. Results indicated equivalent performance.
8. Conclusions:	The performance data demonstrated substantial equivalence.

Table 1: Substantial Equivalence – Similarities and Differences to the XN-Series Automated Hematology analyzers (Modules XN-10, XN-20) and XE-5000 Automated Hematology analyzer.

Features (Submission #)	Predicate XE-5000 (K071967)	XN-Series (XN-10, XN-20)	
FDA Clearance	20-Nov-07	-----	-----
Intended Use	XE-5000	XN-10	XN-20
	Sysmex® XE-5000 is an automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XE-5000 classifies and enumerates the same parameters as the XE-2100 using whole blood as described below, cord blood for HPC and has a body fluid mode for body fluids. The Body Fluid mode analyzes WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF in body fluids (cerebrospinal fluids (CSF), serous fluids, and synovial fluids with EDTA, as needed). WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT% / #, LYMPH% / #, MONO% / #, EO% / #, BASO% / #, NRBC% / #, RDW-SD, RDW-CV, MPV, RET% / #, IRF, IG% / #, RET-He, IPF, HPC WBC-BF, RBC-BF, MN% / #, PMN%/ #, TC-BF#.	The Sysmex® XN-10 module is a quantitative multi-parameter automated hematology analyzer intended for in *vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC#/%, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K_2 or K_3EDTA anticoagulant and, Serous and Synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.	The Sysmex® XN-20 module is a quantitative multi-parameter automated hematology analyzer intended for in *vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC#/%, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K_2 or K_3EDTA anticoagulant and, Serous and Synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.
SIMILARITIES			
Sample Type	Whole blood Body Fluids	Whole Blood Body Fluids	Whole Blood Body Fluids
Principles	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and	SAME	SAME

	SLS-hemoglobin method.		
Parameters	**Whole Blood Mode:** WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He#, IPF. **Body Fluid Mode:** WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#	**Whole Blood Mode:** WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He#, IPF. **Body Fluid Mode:** WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#	**Whole Blood Mode:** WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He#, IPF. **Body Fluid Mode:** WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#
Reagents	SULFOLYSER (Lyse)	SAME	SAME
Principles	Performs hematology analysis according to the RF/DC detection method, Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS hemoglobin method.	SAME	SAME
Modes of Operation	Sampler Analysis Mode Manual Closed Analysis Mode Body Fluid Analysis Mode	SAME	SAME
Measuring Channels	RET/PLT	SAME	SAME
Equivalency Data	Proven performance in FDA submission	Data consisting of Accuracy, Precision, Linearity and Carryover were collected to show performance to the manufacturer's specification for the Body Fluid mode. This analysis supports the claim that the XN-10 analyzer is substantially equivalent to the XE-5000.	Data consisting of Accuracy, Precision, Linearity and Carryover were collected to show performance to the manufacturer's specification for the Body Fluid mode. This analysis supports the claim that the XN-20 analyzer is substantially equivalent to the XE-5000.

DIFFERENCES

Item	**Predicate XE-5000 (K071967)**	**XN-Series (XN-10, XN-20)**	
		XN-10	**XN-20**
Controls & Calibrators	**Whole Blood** e-Check (XE) – 3 Levels Whole Blood Stability Unopened 84 days XE Calibrator	**Whole Blood** *XN-Check – 3 Levels Whole Blood Stability Unopened 84 days *XN-10 Calibrator	**Whole Blood** *XN-Check – 3 Levels Whole Blood Stability Unopened 84 days *XN-20 Calibrator

	(X CAL) **Not Available** **Not Available**	(XN CAL) Platelet F Calibrator (XN CAL PF) **Body Fluid** XN Check BF – 2 Levels *Product name change only.	(XN CAL) Platelet F Calibrator (XN CAL PF) **Body Fluid** XN Check BF – 2 Levels *Product name change only.
IPU	Single Module connect	Multi-Module connect	Multi-Module connect
Modes of Operation	Manual Open Cap Analysis Mode (Operator presents sample to aspiration needle) Capillary Analysis Mode Dilute sample 1:5 Not Available	Manual Open Cap Analysis Mode (Sample placed in tube holder position) Pre-dilute Analysis Mode Dilute sample 1:7 Low WBC Mode (LWBC)	Manual Open Cap Analysis Mode (Sample placed in tube holder position) Pre-dilute Analysis Mode Dilute sample 1:7 Low WBC Mode (LWBC)
Sample Type	Umbilical Cord Blood	Not Available	Not Available
Parameters	HPC	Not Available	Not Available
Sample Aspiration /Fluidic Pathway	Two pathways	Single pathway	Single pathway
Dimensions of Main Unit (Including Sampler Unit)	Width: 706mm Height: 711mm Depth: 912mm	Width: 645mm Height: 855mm Depth: 755mm (Single Unit)	Width: 645mm Height: 855mm Depth: 755mm (Single Unit)
Weight (kg) Including Sampler	93 (Single Unit)	78 (Single Unit)	78 (Single Unit)
Software/Hardware	No Rules-based rerun / reflex	Rules-based rerun / reflex	Rules-based rerun / reflex
Throughput	**Whole Blood** Approximately 113-150 depending on mode used. **Body Fluid** 38 samples/hour	**Whole Blood** 100 samples/hour maximum depending on mode used. **Body Fluid** 40 samples/hour maximum	**Whole Blood** 100 samples/hour maximum depending on mode used. **Body Fluid** 40 samples/hour maximum
Measuring Channels (see Section 11 for detailed information on these channels)	WBC/BASO DIFF NRBC IMI Not Available	WNR WDF WNR Not Available PLT-F	WNR WDF WNR WPC PLT-F
Reagents	CELLPACK™ (Diluent) CELLSHEATH™ (Diluent) STROMATOLYSER-FB™	CELLPACK™ DCL (Diluent) CELLPACK™ DFL	CELLPACK™ DCL (Diluent) CELLPACK™ DFL (Diluent) LYSERCELL WNR (Lyse)

	(Lyse) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) STROMATOLYSER-NR™ (Diluent) STROMATOLYSER-NR™ (Stain) RET-SEARCH II (Diluent) RET-SEARCH II (Stain) STROMATOLYSER-IM™ (Lyse)	(Diluent) LYSERCELL WNR (Lyse) LYSERCELL WDF (Lyse) FLUOROCELL WNR (Stain) FLUOROCELL WDF (Stain) FLUOROCELL RET (Stain) FLUOROCELL PLT (Stain)	LYSERCELL WDF (Lyse) FLUOROCELL WNR (Stain) FLUOROCELL WDF (Stain) FLUOROCELL RET (Stain) FLUOROCELL PLT (Stain) LYSERCELL WPC (Lyse) FLUOROCELL WPC (Stain)
Sample Aspiration Volume	Sampler Mode – 200µL Manual (Closed Cap) Mode - 200µL Manual (Open Cap) Mode - 130µL Capillary Mode - 130µL Body Fluid Mode - 130µL	Sampler Mode – 88µL Manual (Closed Cap) Mode - 88µL Manual (Open Cap) Mode - 88µL Dilution Mode - 70µL Body Fluid Mode - 88µL	Sampler Mode – 88µL Manual (Closed Cap) Mode - 88µL Manual (Open Cap) Mode - 88µL Dilution Mode - 70µL Body Fluid Mode - 88µL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 19 2012

Sysmex America, Inc.
c/o Ms. Sharita Brooks
Clinical Affairs Specialist II
577 Aptakisic Road
Lincolnshire, IL 60069

Re: k112605
Trade/Device Name: Sysmex® XN-Series (XN-10, XN-20) Automated Hematology Analyzers
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: October 15, 2012
Received: October 16, 2012

Dear Ms. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in you Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D
Director
Division Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K112605

Device Name: XN-Series (XN-10, XN-20) Automated Hematology Analyzers

Indications for Use:

The XN-Series modules (XN-10, XN-20) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories.

The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC#/%, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K_2 or K_3EDTA anticoagulant and, Serous and Synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K112605